

portion of the conduit being adhered to a portion of the backing plate, the first portion extending from a first location to a second location, the first location being near the distal end of the tubular conduit, the second location being spaced apart from the first location in a direction towards a center of the generally elliptical inflatable ring.

27. (Amended) A laryngeal mask construction [for airway service to a patient's laryngeal inlet and for removal of gastric-discharge products from the patient's esophagus, the construction] including:

- (A) a mask [portion] adapted for positioning inside of a patient near the patient's larynx, a central plane dividing the construction into a left portion and a right portion;
- (B) an airway tube [extending from a proximal end to a distal end, the distal end of the airway tube being] coupled to the mask [portion], at least a portion of the airway tube extending away from the mask and defining a central axis, the central axis of the portion of the airway tube being disposed on one side of the central plane [the central axis of the airway tube being disposed on one side of a sagittal plane when the mask portion is disposed inside the patient near the patient's larynx, the sagittal plane substantially bisecting the patient into a left half and a right half]; and
- (C) a gastric discharge tube [extending from a proximal end to a distal end, the distal end of the discharge tube being] coupled to the mask [portion], at least a portion of the discharge tube extending away from the mask and defining a central axis, the central axis of the portion of the discharge tube being disposed on the other side of the central plane [the central axis of the discharge tube being disposed on the other side of the sagittal plane when the mask portion is disposed inside the patient near the patient's larynx].

30. (New) A device, including:

- (A) an airway tube for supplying air to a patient;
- (B) an evacuation tube for communication with an esophageal inlet of the patient;
- (C) a mask adapted for sealed engagement with a laryngeal inlet of the patient, the mask including a back cushion for contacting a pharyngeal wall of the patient and biasing at least part of the mask away from the pharyngeal wall, the back cushion defining a periphery, a first portion of the back cushion being sealed to a first portion of the evacuation tube, the first portion of the back cushion being spaced apart from the periphery.

31. (New) A device according to claim 30, the evacuation tube defining a proximal end and a distal end, the distal end being adapted for communication with the esophageal inlet of the patient, a segment of the evacuation tube extending from the distal end towards the proximal end being sealed to the back cushion.

32. (New) A device according to claim 30, a second portion of the evacuation tube being sealed to the mask, the second portion being disposed opposite to the first portion.

33. (New) A device according to claim 30, the mask including a generally elliptical inflatable ring.

34. (New) A device according to claim 33, the mask further including a body, a second portion of the evacuation tube being sealed to the body.

35. (New) A device according to claim 34, the body defining a slot, the evacuation tube extending along the slot.

36. (New) A device including:

(A) an inflatable mask adapted for sealed engagement with a laryngeal inlet of the patient;

(B) a single airway tube for supplying air to a patient, the airway tube being coupled to the mask, a portion of the airway tube extending away from the mask;

(C) a single evacuation tube for communication with an esophageal inlet of the patient, the evacuation tube being coupled to the mask, a portion of the evacuation tube extending away from the mask, the portions of the airway and evacuation tubes being coupled to one another in side-by-side relation such that a center of one of the airway and evacuation tubes is disposed on a left side of the device and a center of the other one of the airway and evacuation tubes is disposed on a right side of the device.

37. (New) A device according to claim 36, the evacuation tube including a conduit extending through a portion of the mask.

38. (New) A device according to claim 37, further including an inflation line coupled to the mask for inflating and deflating the mask.

REMARKS

This paper is filed in response to the Office Action dated June 4, 2002.

Claims 1-38 are currently pending in this application, and of these claims 1, 13, 14, 23, 24, 25, 26, and 27, 30, and 36 are independent. Claims 25 and 27 have been amended and new claims 30-38 have been added to more clearly define the applicant's invention. No new matter is added.

The office action objects to the drawings. The office action also rejects claims 27-29 under 35 U.S.C. 112, first paragraph. The office action also rejects claims 25, 27, and 29 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,355,879 (the "879 patent"). The office action also rejects claim 28 under 35 U.S.C. 103(a) as being unpatentable over the '879 patent. Applicant acknowledges with appreciation that claims 1-24 and 26 have been allowed.

I. Independent Claims 25 and 30

The office action rejects independent claim 25 under 35 U.S.C. 102(b) as being anticipated by the '879 patent. Referring to Figures 2 and 8 of the present application, the tube 26 is adhered to back panel 25 at region 39. As shown specifically in Figure 2, the region 39 extends inward from the periphery of panel 25. This stands in contrast to the '879 patent which may teach that the periphery of panel 50 is sealed to tube 51 but does not teach sealing inner portions of the panel 50 to tube 51. As described in the present application, adhering tube 26 to panel 25 at region 39 advantageously provides a lifting force that helps to hold tube 26 open (see, e.g., col. 6, lines 18-23 of U.S. Patent No. 5,878,745).

Independent claim 25 has been amended to specify that a first portion of the conduit is adhered to a portion of the back cushion, "the first portion extending from a first location to a second location, the first location being near the distal end of the tubular conduit, the second location being spaced apart from the first location in a direction towards a center of the generally elliptical inflatable ring". The art of record is not believed to teach or suggest such a structure. Accordingly, claim 25 is believed to be patentable.

Similar comments apply to new independent claim 30. Accordingly, new independent claim 30, and claims 31-35 which depend therefrom, are believed to be patentable.

II. Independent Claims 27 and 36

A. Rejection under 35 U.S.C. 112, first paragraph

The office action rejects independent claim 27 under 35 U.S.C. 112, first paragraph. In particular, the office action states that the “sagittal plane [of claim 27] and its relative position with respect to each of the airway tube and evacuation tube is not supported by the specification as originally filed”. Applicant respectfully disagrees. In an Information Disclosure Statement filed herewith, applicant has cited several pages from the prior art Concise Medical Dictionary. As shown at page 583 of the cited dictionary, the term “sagittal plane” is well understood by those of ordinary skill. One skilled in the art reading the present application would understand completely the geometric relationships between the sagittal plane and all parts of the laryngeal mask devices disclosed therein. However, to advance the prosecution, applicant has cancelled all references to the sagittal plane from claim 27. Thus, the rejection of claim 27 under 35 U.S.C. 112, first paragraph, and the objection to the drawings is traversed.

Claim 27 now refers to a “central plane”. An example of such a central plane is shown in the present application in Figure 11 at 58.

B. Rejection under 35 U.S.C. 102(b)

The office action also rejects independent claim 27 under 35 U.S.C. 102(b) as being anticipated by the ‘879 patent. More particularly, the office action states:

Applicant’s assertion that evacuation tube (51) and airway tube (11) of Brain (‘879) are not oriented on either side of a sagittal plane are disagreed with because (col. 4, lines 23-35) expressly disclose a side by side relationship and because the tubes as illustrated in fig. 5 are not bonded together beyond the backing plate which leaves them to be oriented in any side by side relationship including one which places them on either side of a sagittal plane, such an orientation following the contours of a patient’s pharyngeal anatomy.

Applicant respectfully submits that there are two errors in the above-quoted statement from the office action. First, the ‘879 patent does NOT “expressly disclose a side by side relationship”. The full text (at col. 4 of the ‘879 patent) cited by the office action for this proposition reads as follows:

In the embodiment of FIG. 5, the softly pliant shell 50 of the invention is applied to still another one of the mask structures of said U.S. patent application Ser. No. 08/003,900, namely, a construction which features

an evacuation tube 50 which extends alongside the airway tube 11 and the body 52 of a laryngeal mask. (emphasis added)

As an initial matter, it should be noted that the '879 patent states that the evacuation tube and airway tube extend "alongside" one another. The '879 patent does not state that these tubes are "side by side". Second, the figure of the '879 patent to which the above-quoted text refers (i.e., Figure 5) clearly shows that the evacuation tube 50 is disposed above the airway tube 11. This stands in contrast to the side by side relationship shown for example in Figures 1, 2, and 10 of the present application. Comparing Figures 1 and 5 of the '879 patent with Figure 1 of the present application, it can immediately be appreciated that there is a significant difference between (a) disposing the evacuation tube above the airway tube and (b) disposing the evacuation and airway tubes in a side by side relationship. Referring first to Figure 1 of the '879 patent, it can be seen that the patient's upper teeth must be separated from the lower teeth by a distance large enough to allow the tubes to extend between the teeth. Or in other words, the inter dental gap must be large enough to accommodate the tubes. If the evacuation tube is disposed above the airway tube, the inter dental gap must be at least as large as the sum of the diameters of the airway and evacuation tubes. On the other hand, if the airway and evacuation tubes are disposed side by side, as taught in the present application, then the inter dental gap need only be as large as the diameter of the largest of the two tubes. So, disposing the evacuation and airway tubes in a side by side configuration advantageously reduces the size of the necessary inter dental gap. Reducing the size of the inter dental gap is important in several instances such as when the laryngeal mask airway device is to be installed for long periods of time or when the patient has injuries or other conditions making it difficult to manipulate the jaw. The side by side arrangement of the present application also has additional advantages over the "one above the other" arrangement of the '879 patent. For example, arranging the airway and evacuation tubes in a "side by side" configuration makes it easier for the tubes to flex in directions required to allow the tubes to be inserted and withdrawn from the patient while following the curve of the patient's airway as shown generally in Figure 1.

The second error in the above-quoted statement from the office action is the statement that the airway and evacuation tubes of the '879 patent "are not bonded together beyond the backing plate which leaves them to be oriented in any side by side relationship including one which places them on either side of a sagittal plane, such an orientation following the contours of

a patient's pharyngeal anatomy". The '879 patent only briefly discusses the Figure 5 embodiment (which shows the evacuation tube 51). However, the '879 patent describes the Figure 5 embodiment by referring to U.S. Patent Application Serial No. 08/003,900, now U.S. Patent No. 5,303,743. The '743 patent itself describes embodiments that provide drainage by referring to U.S. Patent Application Serial No. 919,289, filed Jul. 24, 1992 (see '743 patent at column 8, lines 19-23). In the Information Disclosure Statement filed herewith, applicant has provided a copy of the '289 application as it was filed on July 24, 1992. The '289 application clearly discloses that the airway and evacuation tubes are bonded together along their length beyond the mask portion (see, e.g., the '289 application at page 7, lines 26-28; page 9, lines 26-27; page 10, lines 18-20; page 11, lines 1-3). It is respectfully submitted that the '879 patent should be understood as disclosing airway and evacuation tubes that are bonded together along their lengths beyond the mask portion as is clearly disclosed in the indirectly cited '289 application.

For at least these reasons, applicant respectfully submits that the prior art does not teach or suggest the structure recited in claim 27. Similar comments apply to new independent claim 36. Accordingly, independent claim 27, independent claim 36, and claims 37-38, which depend from claim 36, are believed to be patentable.